



Our Reference: CRMTS #8347  
BL 125398/0

Division of Blood Applications  
Telephone: (301) 827-3524

Novo Nordisk Inc.  
Attention: Mr. Robert Fischer  
100 College Road West  
Princeton, NJ 08540

Dear Mr. Fischer:

Attached is a copy of the memorandum summarizing your March 15, 2012 Type C meeting with CBER. Please note that although cited in the summary, we have not attached copies of materials you supplied. This memorandum constitutes the official record of the meeting. If your understanding of the outcomes differs from those expressed in this meeting summary, it is your responsibility to bring these discrepancies to CBER's attention for resolution.

If you have any questions, please contact Debbie Cordaro at (301) 827-6157.

Sincerely yours,

Iliana Valencia  
Chief  
Regulatory Project Management Branch  
Office of Blood Research and Review  
Center for Biologics  
Evaluation and Research

Enclosure